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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Austin W. Zhang  
Pharmacia & Upjohn Company  
Global Intellectual Property  
301 Henrietta Street  
Kalamazoo, MI 49001

EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/078,611

Applicant(s)

MCCALL ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a method of treating sexual disturbances in a **human** utilizing a sexually therapeutically effective amount of a compound of the formula (A), classified in class 514, subclass 222.8, 224.5, 230.2, 268, 243, 294, 360, 362, and, 387.
- II. Claims 3-4, drawn to a method of inducing mating in a **non-human mammal** utilizing a sexual mating amount of a compound of the formula (A), classified in class 514, subclass 222.8, 224.5, 230.2, 268, 243, 294, 360, 362, and, 387.
- III. Claims 5-6, drawn to a method of **treating a sexual deficiency state** in a **human who has epilepsy, craniopharyngioma, hypogonadism or who has had hysterectomyoophorectomy, hysterectomy or oophorectomy** utilizing a sexually therapeutically effective amount of a compound of the formula (A), classified in class 514, subclass 222.8, 224.5, 230.2, 268, 243, 294, 360, 362, and, 387.
- IV. Claims 7-8, drawn to a method **of increasing sexual desire, interest or performance** in a **human** who is desirous thereof utilizing a sexually useful effective amount of a compound of the formula (A), classified in

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class 514, subclass 222.8, 224.5, 230.2, 268, 243, 294, 360, 362, and, 387.

- V. Claims 9-10, drawn to a compound and pharmaceutically acceptable salts thereof, classified in class 546, subclass 82.

The inventions are distinct, each from the other because of the following reasons:

Inventions I - IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the invention of Group I functions to treat **sexual disturbances in human**; the invention of Group II functions to **induce mating in a non-human mammal**; the invention of Group III functions to treat a **sexual deficiency state in a human who has epilepsy, craniopharyngioma, hypogonadism or who has had hysterectomyoophorectomy, hysterectomy or oophorectomy**; and the invention of Group IV functions to increase **sexual desire, interest or performance in human who is desirous thereof**.

Inventions V and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case inventions I-IV are drawn to the process of treating various sexually related conditions in human as well as in non-human mammal; the invention of Group V is drawn to a chemical compound

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product in such processes. The product as claimed can be used in a materially different process of using that product such as in the treatment of panic attacks, eating disorder, and obsessive compulsive disturbances.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Election of Species***

Claims 1, 3, 5, and 7 are generic to a plurality of disclosed patentably distinct species comprising administering a sexually effective amount of a compound of formula (A) or a combination of a compound of formula (A) and a vascular smooth muscle relaxation agent. Compounds of formula (A) recited in the claims are a generic representation of multiple patentably distinct species such as, for example:

When  $n = 1$ , and when

A is  $\text{SO}_2$ , B is  $\text{NH}$ , and D is  $\text{CH}_2$ , the compound is classified in class 514, subclass 222.8;

A is  $\text{SO}_2$ , B is  $\text{CH}_2$ , and D is  $\text{CH}_2$ , the compound is classified in class 514, subclass 224.5;

A is  $\text{CH}_2$ , B is  $\text{CH}_2$ , and D is  $\text{O}$ , the compound is classified in class 514, subclass 230.2;

A is  $\text{CH}_2$ , B is  $\text{NH}$ , and D is  $\text{CH}_2$ , the compound is classified in class 514, subclass 268;

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A is N, B is CH<sub>2</sub>, and D is NH, the compound is classified in class 514, subclass 243;

A is CH<sub>2</sub>, B is CH<sub>2</sub>, and D is CH<sub>2</sub>, the compound is classified in class 514, subclass 294;

When n= 0, and when

A is SO<sub>2</sub> and D is O, the compound is classified in class 514, subclass 360;

A is SO<sub>2</sub> and D is N, the compound is classified in class 514, subclass 362;

A is C=O and D is N, the compound is classified in class 514, subclass 387;

Applicant is required to elect a single compound of formula A useful in the elected method of treatment.

Furthermore, if the invention of Group III is elected, since the sexual deficiency states may result from separate and distinct causes, which are a generic representation of a multiple patentably distinct species such as for example epilepsy, craniopharyngioma, hypogonadism, hysterectomyoophorectomy, hysterectomy, and oophorectomy, applicant is required to elect a single causative factor of the deficiency state.

Due to the structural diversity in active compounds herein and the different and unrelated natures of the disorders and causative factors therefor encompassed by the claims, the search for all species presents an undue burden on the office. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of compound of formula A and causative factor if Group III is elected, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
June 28, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200